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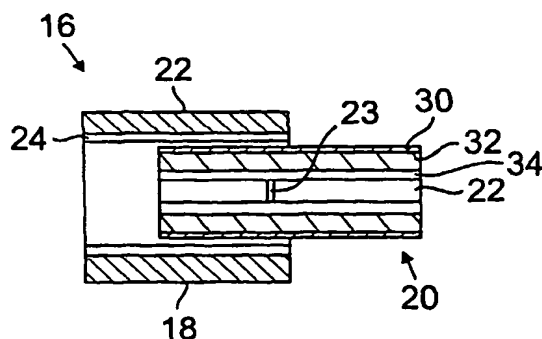
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(54) Title: PORT TUBE AND CLOSURE COMPOSITION, STRUCTURE AND ASSEMBLY FOR A FLOWABLE MATERIAL CONTAINER



(57) Abstract: The present invention provides a flowable material container closure assembly having a port tube and a membrane tube. The port tube has a first layer and a second layer, the first layer is a polymer blend and the second layer is disposed coaxially within the first layer; and the membrane tube is disposed coaxially within the port tube, the membrane tube has an outer layer, a core layer and an inner layer.

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**PORT TUBE AND CLOSURE COMPOSITION, STRUCTURE
AND ASSEMBLY FOR A FLOWABLE MATERIAL CONTAINER**

DESCRIPTION

TECHNICAL FIELD:

The present invention relates generally to closures for flowable material containers and more particularly port tube assemblies for medical fluid containers.

5 BACKGROUND OF THE INVENTION:

It is common medical practice to provide fluids to a patient either intravenously or enterally as a method of treating a patient for various medical conditions. Frequently, the fluids to be administered to a patient are contained in a flexible container. One method of forming a flexible container is to seal two sheets of flexible material about the periphery of the sheets to create a fluid
10 tight chamber. A port tube assembly is frequently placed between the sheets during the sealing process to create a communication between the fluid chamber and the exterior of the container to provide a means of introducing fluid into or dispensing fluid from the container. The port tube assembly typically includes an outer port tube that attaches to the sidewalls of the container and a second tube called a membrane tube is disposed coaxially within the port tube. The membrane tube
15 has a membrane or diaphragm that seals the port tube assembly. The membrane is typically punctured by a spike of a fluid administration set to place the contents of the container in fluid communication with a patient.

Port tubes and membrane tubes are fabricated from monolayer or multiple layered materials. The port tube typically has an inner layer of polyvinyl chloride and the membrane tube has an outer
20 layer of PVC. To assemble the port tube assembly, the membrane tube is dipped in cyclohexanone or other suitable solvent and is inserted in a telescoping fashion into the port tube. The solvent melts the PVC of both the port tube and the membrane tube thereby hermetically sealing the membrane tube to the port tube.

There has been a great effort by many manufacturers of medical articles to replace PVC
25 materials with non-PVC containing materials. Flexible PVC containers include low molecular weight additives known as plasticizers which may exude into the solutions contained in the container. United States Patent Nos. 5,998,019 and 5,849,843, which are incorporated herein by reference and made a part hereof, disclose replacing PVC materials in medical fluid containers with

non-PVC containing materials.

United States Patent No. 5,356,709, assigned to the same assignee of the present invention, discloses a non-PVC coextruded medical grade port tubing. The tubing has an outer layer of a blend of polypropylene and SEBS a tie layer and a core layer of a blend of polyamide and EVA.

5 United States Patent No. 5,533,992, assigned to the same assignee of the present invention, discloses a non-PVC material for fabricating medical tubings and medical containers. Polymer blends for fabricating medical tubing disclosed in the '992 Patent include polyurethane blended with one or more of the following: EVA, SEBS, PCCE, thermoplastic copolyester elastomers.

10 SUMMARY OF THE INVENTION:

The present invention provides a non-PVC port tube, a non-PVC membrane tube and a non-PVC port tube assembly for use in flowable material containers such as medical and food containers.

The closure assembly includes a port tube and a membrane tube coaxially mounted therein.

15 The port tube has a first layer and a second layer. The first layer is a multiple component polymer blend having a first component in an amount by weight of from about 25% to about 50% by weight of the first layer. The first component is a first polyolefin selected from the group consisting of polypropylene and polypropylene copolymers. The second component is present in an amount by weight of from about 0% to about 50% by weight of the first layer and is a second polyolefin. The

20 second polyolefin is selected from the group consisting of ethylene copolymers, ultra-low density polyethylene, polybutene, polybutadiene and butene ethylene copolymers. The third component is present in an amount by weight of from about 0% to about 40% by weight of the first layer and is a radio frequency ("RF") susceptible polymer. The RF polymer is selected from the group consisting of polyamides, ethylene acrylic acid copolymers, ethylene methacrylic acid copolymers;

25 polyimides, polyurethanes, polyesters, polyureas, ethylene vinyl acetate copolymers with a vinyl acetate comonomer content from 12%-50% by weight of the copolymer, ethylene methyl acrylate copolymers with methyl acrylate comonomer content from 12%-40% by weight of the copolymer;

30 ethylene vinyl alcohol with vinyl alcohol comonomer content from 12%-70% by mole percent of the copolymer. The fourth component is present in an amount from about 0% to about 40% and is a first thermoplastic elastomer.

The second layer of the port tube is disposed coaxially within the first layer and in a preferred form of the invention is a polymeric material that is susceptible of solvent bonding and

more preferably includes a second thermoplastic elastomer. Optionally, the second layer can include an additive from about 0% to about 20% by weight of a polypropylene, high density polyethylene, silica, slip agents, fatty amides, acrawax and the like.

5 The membrane tube has an outer layer, a core layer and an inner layer. The outer layer of the membrane tube is capable of being solvent bonded to the second layer of the port tube. In a preferred form of the invention, the outer layer of the membrane tube (A) is a polymer blend of: (1) from about 0% to about 60% by weight of the outer layer of a third polyolefin and (2) from about 40% to about 100% by weight of the outer layer of a second component of a third thermoplastic elastomer. The core layer (B) is attached to the outer layer. In a preferred form of the invention, the core layer is a polymer blend of: (1) from about 35% to about 100% by weight of the core layer of a fourth thermoplastic elastomer and (2) from about 0% to about 65% by weight of the core layer of a fourth polyolefin.

10 The inner layer of the membrane tube is attached to the core layer on a side opposite of the outer layer. The inner layer is a multiple component polymer blend of and in a preferred form has: (1) from about 25% to about 55% by weight of the inner layer a fifth polyolefin, (2) from about 0% to about 50% by weight of the inner layer a sixth polyolefin selected from the group consisting of ethylene copolymers, ultra-low density polyethylene, polybutene, and butene ethylene copolymers; (3) from about 0% to about 40% by weight of the inner layer of a radio frequency susceptible polymer selected from the group consisting of polyamides, ethylene acrylic acid copolymers, ethylene methacrylic acid copolymers, polyimides, polyurethanes, polyesters, polyureas, ethylene vinyl acetate copolymers with a vinyl acetate comonomer content from 12%-50% by weight of the copolymer, ethylene methyl acrylate copolymers with methyl acrylate comonomer content from 12%-40% by weight of the copolymer, ethylene vinyl alcohol with vinyl alcohol comonomer content from 12%-70% by mole percent of the copolymer; and (4) from about 0% to about 40% by weight of the inner layer of a fifth thermoplastic elastomer.

25 These and other aspects and attributes of the present invention will be discussed with reference to the following drawings and accompanying specification.

BRIEF DESCRIPTION OF THE DRAWINGS:

30 FIG. 1 is a plan view of a flowable material container with port closure assembly; and
FIG. 2 is a cross-sectional view of a port tube of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is susceptible of embodiments in many different forms. Preferred embodiments of the invention are disclosed with the understanding that the present disclosure is to be considered as exemplifications of the principles of the invention and are not intended to limit the broad aspects of the invention to the embodiments illustrated.

FIG. 1 shows a flowable material container **10** having sidewalls **12** sealed along peripheral edges to define a chamber **14** therebetween. A port tube closure assembly **16** provides access to the contents of the container. The container **10** is preferably fabricated from a non-PVC containing material. In a preferred form of the invention, the sidewalls **12** are fabricated from a multiple component polymer alloy such as those disclosed in detail in U.S. Patent No. 5,686,527 which is incorporated herein by reference and made a part hereof. One particularly suitable polymer alloy is a blend of polypropylene, ultra-low density polyethylene, a polyamide and a styrene and hydrocarbon block copolymer. The container **10** shown in FIG. 1 is particularly suitable for medical applications such as storage and delivery of I.V. solutions, peritoneal dialysis solutions, pharmaceutical drugs and blood and blood components to name a few. It is contemplated that such a container can also be used to store food products, serve as a drain bag for peritoneal dialysis or store other consumable products.

What is meant by "flowable material" is a material that will flow by the force of gravity. Flowable materials therefore include both liquid items and powdered or granular items and the like.

FIG. 2 shows the port tube assembly **16**. The port tube assembly **16** has a port tube **18** and a membrane tube **20** coaxially mounted therein. A fluid passageway **22** of the membrane tube **20** is sealed by a membrane **23** positioned at an intermediate portion of the membrane tube **20**. For medical applications, the membrane **23** can be punctured by a spike of an infusion set to place the contents of the container into fluid communication with, for example, the vascular system of a patient being treated.

In a preferred form of the invention, the port tube **18** is a multilayered structure and more preferably has a first layer **22** and a second layer **24**. The first layer **22** should be of a non-PVC containing material that is capable of being sealed to the sidewalls **12** of the container **10**, and preferably sealed using radio frequency sealing techniques. In a preferred form of the invention the first layer **22** is a polymer blend of: (a) from about 25% to about 50%, more preferably from about 30% to about 40%, by weight of the first layer a first polyolefin selected from the group consisting of polypropylene and polypropylene copolymers, (b) from about 0% to about 50%, more preferably

from about 5% to about 40%, by weight of the first layer a second polyolefin of an α -olefin containing polymer or copolymer and more preferably is an ethylene and α -olefin copolymer; (c) from about 0% to about 40%, more preferably from about 10% to about 40% of the first layer; a radio frequency susceptible polymer selected from the group consisting of polyamides, ethylene acrylic acid copolymers, ethylene methacrylic acid copolymers, polyimides, polyurethanes; 5 polyesters, polyureas, ethylene vinyl acetate copolymers with a vinyl acetate comonomer content from 12%-50% by weight of the copolymer, ethylene methyl acrylate copolymers with methyl acrylate comonomer content from 12%-40% by weight of the copolymer, ethylene vinyl alcohol with vinyl alcohol comonomer content from 12%-70% by mole percent of the copolymer; and (d) 10 from about 0% to about 40%, more preferably from about 10% to about 40% of a thermoplastic elastomer by weight of the first layer.

The second layer 24 of the port tube 18 is of a non-PVC containing material that is capable of being solvent bonded to the membrane tube 20. In a preferred form of the invention the second layer 24 is a thermoplastic elastomer or a blend of a thermoplastic elastomer in an amount by 15 weight of from about 80% to about 100% and a propylene containing polymer from about 0% to about 20% by weight of the second layer 24. It is also desirable, but optional, that the second layer 24 softens slightly at autoclave temperatures so that when the port tube and membrane tube assembly is steam sterilized, the port tube more tightly adheres to the membrane tube.

As shown in the Figures, the first layer has a thickness greater than the second layer. In a 20 preferred form of the invention the first layer will have a thickness of from about 15 mils to about 40 mils and more preferably from about 20 mils to about 30 mils. The second layer will have a thickness from about 2 mils to about 10 mils and more preferably from about 3 mils to about 7 mils.

The membrane tube 20 should be fabricated from a non-PVC containing material and 25 should be capable of being bonded to the port tube 18, preferably using solvent bonding techniques. Solvent bonding is well known in the art. Solvent bonding typically includes applying a solvent to a polymeric material to partially dissolve the polymer. While in this dissolved state the dissolved polymer material is placed in contact with a material, such as another polymer, that the polymeric material is to be bonded to. Suitable solvents for solvent bonding of the materials of the present 30 invention include at least the following aromatic solvents: cyclohexane, cyclohexanone, toluene, tetrahydrofuran, cumene, xylenes, diethyl benzene, decalin, tetralin and amyl benzene to name a few.

Accordingly, to solvent bond the membrane tube to the port tube, a portion of the membrane tube that is to be in contact with the port tube is exposed to the solvent, typically by dipping the relevant portion of the membrane tube into the solvent. Then the membrane tube is inserted into the membrane tube in telescoping fashion where a strong bond is formed.

5 In a preferred form of the invention, the membrane tube 20 is a multilayered structure having an outer layer 30, a core layer 32, and an inner layer 34. In a preferred form of the invention, the outer layer 30 is a polymer blend of: (a) from about 0% to about 60%, more preferably from about 20% to about 55% and most preferably from about 30% to about 50%, by weight of the outer layer of a polyolefin and (b) from about 40% to about 100%, more preferably from about 45% to about 80% and most preferably from about 50% to about 70%, by weight of the
10 outer layer of a thermoplastic elastomer.

Also, in a preferred form of the invention, the core layer 32 is a polymer blend of: (a) from about 35% to about 100%, more preferably from about 50% to about 90% and most preferably 70% to about 90%, by weight of the core layer of a thermoplastic elastomer and (b) from about 0% to about 65%, more preferably from about 10% to about 50% and most preferably from about 10%
15 to about 30%, by weight of the core layer of a polyolefin.

Also, in a preferred form of the invention, the inner layer 34 is a polymer blend of: (a) from about 25% to about 55%, more preferably from about 25% to about 40%, by weight of the inner layer a polyolefin; (b) from about 0% to about 50%, more preferably from about 0% to about 40% and most preferably 0% to about 20%, by weight of the inner layer a polyolefin selected from the group consisting of α -olefin containing polymers or copolymers and more preferably is an ethylene and α -olefin copolymer; (c) from about 0% to about 40% by weight, more preferably from about 15% to about 40%, of the inner layer a radio frequency susceptible polymer selected from the group consisting of polyamides, ethylene acrylic acid copolymers, ethylene methacrylic acid copolymers,
20 polyimides, polyurethanes, polyesters, polyureas, ethylene vinyl acetate copolymers with a vinyl acetate comonomer content from 12%-50% by weight of the copolymer, ethylene methyl acrylate copolymers with methyl acrylate comonomer content from 12%-40% by weight of the copolymer, ethylene vinyl alcohol with vinyl alcohol comonomer content from 12%-70% by mole percent of the copolymer; and (d) from about 0% to about 40%, more preferably from about 15% to about
25 40%, by weight of the inner layer of a thermoplastic elastomer.

In a preferred form of the invention, the outer layer 30 will have a thickness from about 3 mils to about 15 mils and more preferably from about 3 mils to about 10 mils. The core layer 32

will have a thickness from about 10 mils to about 35 mils and more preferably from about 10 mils to about 30 mils. The inner layer 34 will have a thickness from about 3 mils to about 15 mils and more preferably from about 5 mils to about 10 mils.

Thermoplastic elastomers include styrene and hydrocarbon copolymers, EPDM, and ethylene propylene rubber. The styrene can be substituted or unsubstituted styrene. The styrene and hydrocarbon copolymers can be block copolymer including di-block, tri-block, star block, it can also be a random copolymer and other types of styrene and hydrocarbon copolymers that are known by those skilled in the art. Styrene and hydrocarbon copolymers therefore include for example, but are not limited to, styrene-butene-styrene block copolymer, styrene-ethylene-butene-styrene block copolymers, styrene-isobutene-styrene and the numerous other varieties of styrene and hydrocarbon copolymers that are well known in the art. The styrene and hydrocarbon copolymers can also be blends of various types of the above-identified styrene and hydrocarbon copolymers.

The styrene and hydrocarbon copolymers can be modified or functionalized by carboxylic acid groups, anhydrides of carboxylic acids, esters of carboxylic acids, epoxy groups and carbon monoxide. In a preferred form of the invention, the thermoplastic elastomer of the first layer 22 of the port tube 18 and the inner layer 34 of the membrane tube 20 is an SEBS copolymer with a maleic anhydride group in an amount by weight of about 2% or less. Such a copolymer is sold by Shell Chemical Company under the tradename KRATON® FG1924X and FG1901X.

The thermoplastic elastomer of the second layer 24 of the port tube 18 and the outer layer 30 of the membrane tube 20 is preferably a styrene and diene copolymer more preferably selected from the group consisting of styrene-ethylene-butene-styrene copolymers, and styrene-isoprene-styrene copolymers. More preferably the thermoplastic elastomer of the second layer is an ethylene butene copolymer, and more preferably a styrene-ethylene-butene-styrene copolymer. It has been found that such a copolymer is well suited for solvent bonding. Suitable SEBS copolymers are sold by Shell Chemical Company under the tradename KRATON® KG1657.

The thermoplastic elastomer of the core layer of the membrane tube is an SEBS copolymer containing a high proportion of triblock. Suitable polymers are sold by Shell Chemical Company under the tradename KRATON® KG1660, KG1652 and KG1650.

Suitable polypropylene polymers include homopolymers and copolymers. Suitable comonomers are α -olefins having from 2 to 17 carbons and most preferably is ethylene in an amount by weight from about 1 to about 8% by weight of the copolymer.

Suitable α -olefin containing polymers include homopolymers, copolymers and interpolymers of α -olefins having from 2 to 17 carbons. Suitable ethylene α -olefin copolymers of the first layer 22 of the port tube 18 and the inner layer 34 of the membrane tube 20 have a density, as measured by ASTM D-792, of less than about 0.915 g/cc, more preferably less than about 0.905 g/cc, and are commonly referred to as very low density polyethylene (VLDPE), ultra low density polyethylene (ULDPE) and the like. In a preferred form of the invention, the ethylene and α -olefin copolymers are obtained using a single site catalyst such as metallocene catalysts, vanadium catalysts and the like. Suitable catalyst systems, among others, are those disclosed in U.S. Patent Nos. 5,783,638 and 5,272,236. Suitable ethylene and α -olefin copolymers include those sold by Dow Chemical Company under the AFFINITY tradename, Dupont-Dow under the ENGAGE tradename, Exxon under the EXACT tradename and Phillips Chemical Company under the tradename MARLEX.

The port tube assembly, in a preferred form of the invention satisfies the following physical properties: (1) has a spike insertion force of less than about 35 lbs on average, (2) has a spike removal force of greater than about 5 lbs on average. The pull force to separate the membrane tube from the port tube is greater than the spike removal force.

The following is a non-limiting example of the present invention.

Examples:

A two layered port tube having an outer and an inner layer was coextruded. The inner layer had a thickness of 0.006 inches and was fabricated from SEBS. The outer layer had a thickness of 0.026 inches and was fabricated from a polymer blend by weight of the outer layer of 35% polypropylene/5% ultra low density polyethylene/30% dimer fatty acid polyamide/30% SEBS with maleic anhydride functionality.

A three layered membrane tube was coextruded having an inner layer, a core layer and an outer layer. The inner layer is a polymer blend by weight 30% polypropylene/35% dimer fatty acid polyamide/35% SEBS. The core layer was a blend of 85% SEBS and 15% polypropylene. The outer layer was 45% SEBS and 55% polypropylene. The inner layer had a thickness of 0.003 inches, the core layer 0.023 inches and the outer layer 0.006 inches.

Polymeric sheeting was extruded from a blend by weight of 10% dimer fatty acid polyamide, 35% ultra low density polyethylene, 45% polypropylene and 10% SEBS with maleic anhydride functionality.

Two rectangularly-shaped sheets of the polymeric sheeting were placed into registration and

sealed along 3 peripheral edges to define a pouch. A port tube segment was inserted into an open end of the pouch and was heat sealed therein while sealing the final peripheral edge to define a container. A membrane tube segment was dipped into cyclohexanone and inserted in a telescoping fashion into the port tube segment.

5 The container was bolted down proximate a mechanical tester. The port tube was attached to a spike attached to a cross-head of the mechanical tester. The cross-head speed of the tester was set at 20 in/min. The cross-head was set to achieve the desired spike insertion depth in the port tube. The tester allowed for measuring the spike insertion force and the spike removal force. The average spike insertion value after 50 tests was 13.31 lbf. The average spike removal force for 50
10 tests was 10.37 lbf. These measurements were made after the spike dwelled in the membrane tube for 24 hours.

 The tester was also used to determine the pull force necessary to remove the port tube from the container or to otherwise damage the container or port tube. The port tube was inserted into the tester with the container bolted down. The average pull force for 28 tests was 30.04 lbf. This
15 test was conducted prior to steam sterilizing the container. The value for 30 test after the container was steam sterilized was 42.68 lbf.

 From the foregoing, it will be observed that numerous variations and modifications may be effected without departing from the spirit and scope of the invention. It is to be understood that no
20 limitation with respect to the specific apparatus illustrated herein is intended or should be inferred. It is, of course, intended to cover by the appended claims all such modifications as fall within the scope of the claims.

CLAIMS

WE CLAIM:

1. A multiple layered non-PVC containing tubing comprising:
a first layer of a polymer blend of: (a) from about 25% to about 50% by weight of the first layer a first polyolefin selected from the group consisting of polypropylene and polypropylene copolymers, (b) from about 0 to about 50% by weight of the first layer a second polyolefin selected from the group consisting of ethylene copolymers, ultra-low density polyethylene, polybutene, polybutadiene and butene ethylene copolymers; (c) from about 0% to about 40% by weight of the first layer a radio frequency susceptible polymer selected from the group consisting of polyamides, ethylene acrylic acid copolymers, ethylene methacrylic acid copolymers, polyimides, polyurethanes, polyesters, polyureas, ethylene vinyl acetate copolymers with a vinyl acetate comonomer content from 12%-50% by weight of the copolymer, ethylene methyl acrylate copolymers with methyl acrylate comonomer content from 12%-40% by weight of the copolymer, ethylene vinyl alcohol with vinyl alcohol comonomer content from 12%-70% by mole percent of the copolymer; (d) from about 0% to about 40% of a first thermoplastic elastomer; and
a second layer disposed coaxially within the first layer and being a second thermoplastic elastomer.
2. The tubing of claim 1 wherein the polyamide is selected from a group consisting of: aliphatic polyamides resulting from the condensation reaction of diamines having a carbon number within a range of 2-13, aliphatic polyamides resulting from a condensation reaction of di-acids having a carbon number within a range of 2-13, polyamides resulting from the condensation reaction of dimer fatty acids, and amide containing copolymers.
3. The tubing of claim 1 wherein the polyamide is a dimer fatty acid polyamide.
4. The tubing of claim 1 wherein the first polyolefin is a propylene copolymerized with a monomer selected from the group consisting of α -olefins having from 2-17 carbons.
5. The tubing of claim 4 wherein the first polyolefin is a propylene and ethylene copolymer having an ethylene content of from about 1% to about 8% by weight of the first polyolefin.
6. The tubing of claim 1 wherein the first thermoplastic elastomer is selected from the group consisting of a first styrene and hydrocarbon copolymer.
7. The tubing of claim 6 wherein the first styrene and hydrocarbon copolymer is selected from the group of polymers structures with diblock, triblock, radial block, and star block.
8. The tubing of claim 7 wherein the first thermoplastic elastomer is a styrene-ethylene-butene-

styrene block copolymer.

9. The tubing of claim 7 wherein the first thermoplastic elastomer is functionalized with a group selected from the group consisting of carboxylic acid, esters of carboxylic acids, anhydrides of carboxylic acids, epoxides, and carbon monoxide.

10. The tubing of claim 9 wherein the first thermoplastic elastomer is maleic anhydride functionalized.

11. The tubing of claim 1 wherein the second thermoplastic elastomer is selected from the group consisting of a second styrene and hydrocarbon copolymer.

12. The tubing of claim 11 wherein the second styrene and hydrocarbon copolymer is selected from the group of polymer structures with diblock, triblock, radial block, and star block.

13. The tubing of claim 12 wherein the second thermoplastic elastomer is selected from the group consisting of a styrene-ethylene-butene-styrene copolymer, styrene-isoprene-styrene and styrene-ethylene-propylene.

14. The tubing of claim 13 wherein the second thermoplastic elastomer contains styrene-ethylene-butene-styrene diblock copolymer and a styrene-ethylene-butene-styrene triblock copolymer.

15. The tubing of claim 1 wherein the second polyolefin is an ethylene copolymerized with a monomer selected from the group consisting of α -olefins.

16. The tubing of claim 15 wherein the ethylene and α -olefin copolymer is obtained using a single-site catalyst.

17. The tubing of claim 1 wherein the second layer further comprises an additive selected from the group consisting of polypropylene, high density polyethylene, silica, slip agents, fatty amides, and acrawax.

18. The tubing of claim 17 wherein the additive is present in an amount by weight of the second layer from about 0% to about 20%.

19. A multiple layered non-PVC containing tubing comprising:

an outer layer of a polymer blend of: (a) from about 0% to about 60% by weight of the outer layer of a first polyolefin and (b) from about 40% to about 100% by weight of the outer layer of a first thermoplastic elastomer;

a core layer attached to the outer layer, the core layer is a polymer blend of: (a) from about 35% to about 100% by weight of the core layer of a second thermoplastic elastomer and (b) from about 0% to about 65% by weight of the core layer of a second polyolefin; and

an inner layer attached to the core layer on a side opposite of the outer layer, the inner layer being a polymer blend of: (a) from about 25% to about 55% by weight of the inner layer a third polyolefin, (b) from about 0 to about 50% by weight of the inner layer a fourth polyolefin selected from the group consisting of ethylene copolymers, ultra-low density polyethylene, polybutene, and butene ethylene copolymers; (c) from about 0% to about 40% by weight of the inner layer a radio frequency susceptible polymer selected from the group consisting of polyamides, ethylene acrylic acid copolymers, ethylene methacrylic acid copolymers, polyimides, polyurethanes, polyesters, polyureas, ethylene vinyl acetate copolymers with a vinyl acetate comonomer content from 12%-50% by weight of the copolymer, ethylene methyl acrylate copolymers with methyl acrylate comonomer content from 12%-40% by weight of the copolymer, ethylene vinyl alcohol with vinyl alcohol comonomer content from 12%-70% by mole percent of the copolymer; and (d) from about 0% to about 40% by weight of the inner layer of a third thermoplastic elastomer.

20. The tubing of claim 19 wherein the polyamide is selected from a group consisting of: aliphatic polyamides resulting from the condensation reaction of diamines having a carbon number within a range of 2-13, aliphatic polyamides resulting from a condensation reaction of di-acids having a carbon number within a range of 2-13, polyamides resulting from the condensation reaction of dimer fatty acids, and amide containing copolymers.

21. The tubing of claim 19 wherein the polyamide is a dimer fatty acid polyamide.

22. The tubing of claim 19 wherein the first polyolefin is selected from the group consisting of: a polypropylene homopolymer, a propylene copolymerized with a monomer selected from the group consisting of α -olefins having from 2-17 carbons, ethylene homopolymers and ethylene copolymerized with a monomer selected from the group consisting of α -olefins having from 2-17 carbons.

23. The tubing of claim 22 wherein the first polyolefin is a propylene and ethylene copolymer having an ethylene content of from about 1% to about 8% by weight of the first polyolefin.

24. The tubing of claim 19 wherein the second polyolefin is selected from the group consisting of: a polypropylene homopolymer, a propylene copolymerized with a monomer selected from the group consisting of α -olefins having from 2-17 carbons, ethylene homopolymers and ethylene copolymerized with a monomer selected from the group consisting of α -olefins having from 2-17 carbons.

25. The tubing of claim 19 wherein the third polyolefin is selected from the group consisting of: a polypropylene homopolymer, a propylene copolymerized with a monomer selected from the

group consisting of α -olefin s having from 2-17 carbons, ethylene homopolymers and ethylene copolymerized with a monomer selected from the group consisting of α -olefin s having from 2-17 carbons..

26. The tubing of claim 19 wherein the first thermoplastic elastomer is selected from the group consisting of a first styrene and hydrocarbon copolymers.

27. The tubing of claim 26 wherein the first styrene and hydrocarbon copolymer is selected from the group of polymers structures with diblock, triblock, radial block, and star block.

28. The tubing of claim 27 wherein the first thermoplastic elastomer is selected from a first styrene-ethylene-butene-styrene copolymer, styrene-isoprene-styrene copolymer and styrene-ethylene-propylene-styrene copolymer.

29. The tubing of claim 28 wherein the first thermoplastic elastomer is a styrene-ethylene-butene-styrene diblock copolymer and a styrene-ethylene-butene-styrene triblock copolymer.

30. The tubing of claim 19 wherein the second thermoplastic elastomer is selected from the group consisting of a second styrene and hydrocarbon copolymers.

31. The tubing of claim 30 wherein the second styrene and hydrocarbon copolymer is selected from the group consisting of a polymer structure with diblock, triblock, copolymers, styrene and hydrocarbon star block copolymers, and blends containing the same.

32. The tubing of claim 31 wherein the second thermoplastic elastomer is selected from a second styrene-ethylene-butene-styrene copolymer, a second styrene-isoprene-styrene copolymer and a second styrene-ethylene-propylene-styrene copolymer.

33. The tubing of claim 19 wherein the third thermoplastic elastomer is selected from the group consisting of a third styrene and hydrocarbon copolymers.

34. The tubing of claim 33 wherein the third styrene and hydrocarbon copolymer is selected from the group consisting of polymer structure with diblock, triblock, star block copolymers and blends of the same.

35. The tubing of claim 34 wherein the third thermoplastic elastomer is a third styrene-ethylene-butene-styrene block copolymer.

36. The tubing of claim 34 wherein the third thermoplastic elastomer is functionalized with a group selected from the group consisting of carboxylic acid, esters of carboxylic acids, anhydrides of carboxylic acids, epoxides, and carbon monoxide.

37. The tubing of claim 36 wherein the third thermoplastic elastomer is maleic anhydride functionalized.

38. The tubing of claim 19 wherein the fourth polyolefin is an ethylene copolymerized with a monomer selected from the group consisting of α -olefins.
39. The tubing of claim 38 wherein the fourth polyolefin is an ethylene and α -olefin copolymer.
40. The tubing of claim 39 wherein the ethylene and α -olefin copolymer is obtained using a single-site catalyst.

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FIG. 1

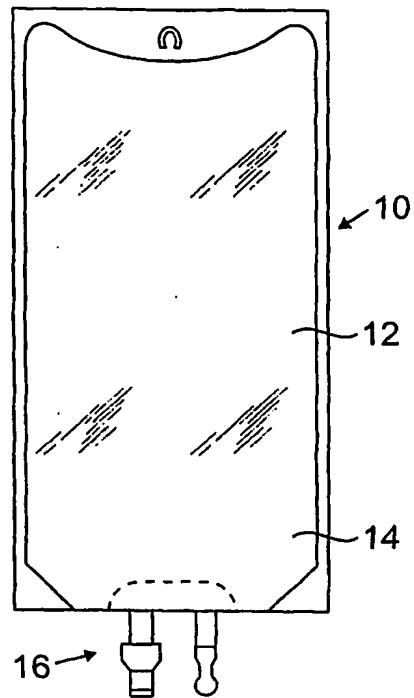
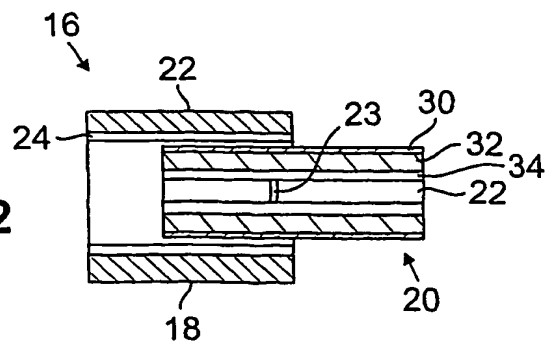


FIG. 2



INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 02/00299

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 B32B1/08 B29C65/04 A61L29/12 C08L23/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61L B29C B29D B32B C08L F16L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 95 13918 A (BAXTER INT) 26 May 1995 (1995-05-26) page 1, paragraph 1 - paragraph 2; claims 1-55; figures 1-10	1-18
Y	EP 0 765 740 A (FRESENIUS AG) 2 April 1997 (1997-04-02) claims 1,4	1-18
A	US 5 529 821 A (ISHIKAWA KENJI ET AL) 25 June 1996 (1996-06-25) claim 43; example 1	1
A	US 6 004 311 A (HEILMANN KLAUS ET AL) 21 December 1999 (1999-12-21) claim 1; figure 1	19
	--- -/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

14 May 2002

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/00299

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 1 059 479 A (MEIJI GOMU KASEI KK ;KONDO TAKESHI (JP); ISHII TOSHINORI (JP); TAN) 13 December 2000 (2000-12-13) claim 1 ---	1
A	US 5 562 127 A (KO JOHN H ET AL) 8 October 1996 (1996-10-08) claim 1; figure 1 ---	1
A	EP 0 623 651 A (WENDELBORN DIETER ;SCHAEFER HELMUT (DE); MOLTRECHT WILFRIED (DE)) 9 November 1994 (1994-11-09) claim 1 ---	1,4-8
A	EP 0 564 231 A (GRACE W R & CO) 6 October 1993 (1993-10-06) claims 1,2 ---	1
A	US 4 588 777 A (HOTTA MASAHIRO) 13 May 1986 (1986-05-13) example 6 ---	1
A	US 5 601 889 A (CHUNDURY DEENADAYALU ET AL) 11 February 1997 (1997-02-11) claim 1 -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/00299

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9513918	A	26-05-1995	US 5998019 A	07-12-1999
			AT 175383 T	15-01-1999
			AU 686285 B2	05-02-1998
			AU 1182395 A	06-06-1995
			BR 9405785 A	12-12-1995
			CA 2153481 A1	26-05-1995
			CN 1117718 A ,B	28-02-1996
			CZ 9501746 A3	17-01-1996
			DE 69415792 D1	18-02-1999
			DE 69415792 T2	19-08-1999
			DK 679124 T3	30-08-1999
			EP 0679124 A1	02-11-1995
			ES 2129189 T3	01-06-1999
			GR 3029456 T3	28-05-1999
			HK 1002389 A1	16-06-2000
			HU 72715 A2	28-05-1996
			JP 8506068 T	02-07-1996
			NO 952802 A	15-09-1995
			NZ 276958 A	27-04-1998
			PL 309919 A1	13-11-1995
			SG 65537 A1	22-06-1999
			TR 27954 A	06-11-1995
			WO 9513918 A1	26-05-1995
			US 6168862 B1	02-01-2001
			US 6261655 B1	17-07-2001
			US 5993949 A	30-11-1999
			ZA 9408817 A	11-07-1995
EP 0765740	A	02-04-1997	DE 19534455 C1	12-12-1996
			AU 699497 B2	03-12-1998
			AU 6213496 A	20-03-1997
			BR 9603732 A	26-05-1998
			CA 2184868 A1	17-03-1997
			EP 0765740 A2	02-04-1997
			JP 9123314 A	13-05-1997
			US 5928744 A	27-07-1999
US 5529821	A	25-06-1996	DE 69329783 D1	01-02-2001
			DE 69329783 T2	05-07-2001
			EP 0577493 A2	05-01-1994
			JP 3233738 B2	26-11-2001
			JP 6070971 A	15-03-1994
US 6004311	A	21-12-1999	DE 19534413 C1	28-05-1997
			AU 707219 B2	08-07-1999
			AU 6430096 A	20-03-1997
			BR 9603731 A	26-05-1998
			CA 2184869 A1	17-03-1997
			EP 0769516 A2	23-04-1997
			JP 9103493 A	22-04-1997
EP 1059479	A	13-12-2000	JP 2001349476 A	21-12-2001
			AU 1691000 A	24-07-2000
			EP 1059479 A1	13-12-2000
			CN 1294668 T	09-05-2001
			WO 0040884 A1	13-07-2000
US 5562127	A	08-10-1996	AU 7327894 A	28-02-1995

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/00299

Patent document cited in search report		Publication date	Patent family member(s) -	Publication date
US 5562127	A		EP 0712354 A1	22-05-1996
			WO 9504652 A1	16-02-1995
EP 0623651	A	09-11-1994	DE 4315003 A1	10-11-1994
			AT 161564 T	15-01-1998
			DE 59404856 D1	05-02-1998
			EP 0623651 A2	09-11-1994
			ES 2113012 T3	16-04-1998
EP 0564231	A	06-10-1993	AT 152964 T	15-05-1997
			CA 2091306 A1	01-10-1993
			DE 69310601 D1	19-06-1997
			DE 69310601 T2	11-09-1997
			EP 0564231 A1	06-10-1993
			ES 2103429 T3	16-09-1997
			JP 6048451 A	22-02-1994
			ZA 9301680 A	05-10-1993
US 4588777	A	13-05-1986	JP 1463605 C	28-10-1988
			JP 59074153 A	26-04-1984
			JP 63009546 B	29-02-1988
			BE 904955 A7	16-10-1986
			DE 3337997 A1	26-04-1984
			GB 2131816 A , B	27-06-1984
			HK 72190 A	21-09-1990
			SE 458859 B	16-05-1989
			SE 8305686 A	30-05-1984
			SG 51189 G	02-03-1990
US 5601889	A	11-02-1997	CA 2136106 A1	30-11-1993
			EP 0642550 A1	15-03-1995
			WO 9324568 A1	09-12-1993